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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,881	02/24/2004	Mark L. Nelson	PAZ-222CN	1902
959	7590	10/11/2006		
LAHIVE & COCKFIELD 28 STATE STREET BOSTON, MA 02109			EXAMINER QAZI, SABIHA NAIM	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/786,881

Applicant(s)

NELSON ET AL.

Examiner

Sabiha Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/24/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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Claims 1-48 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-26 drawn to tetracycline compound and composition of formula (1), when X represents N, classified in class 546, subclass (various).
 - II. Claims 1-26 drawn to tetracycline compounds and compositions of formula (1), when X represents O, classified in class 549, subclass (various).
 - III. Claims 1-26 drawn to tetracycline compounds and compositions of formula (1), when X represents C, classified in class 552, subclass (various).
 - IV. Claims 1-26 drawn to tetracycline compounds and compositions of formula (1), when X represents S, classified in class 549, subclass (various).
 - V. Claims 27-35 drawn to tetracycline compounds and compositions of formula (1I), when X represents S, classified in class 549, subclass (various).
 - VI. Claims 36 and 37 drawn to tetracycline compounds and compositions of formula (1II), when X represents S, classified in class 549, subclass (various).
 - VII. Claims 38-48 are drawn to methods of use of the compound as cited above.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions VII and I to VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). In the instant case several claimed diseases can be treated which other compounds and compositions can treat does not require the composition or compound as presently claimed.

Invention of group I-VI are drawn to different tetracycline compounds, they are different and a reference used to reject the invention of one group may not be used to reject the invention of any other group for the same reasons.

3. These inventions are independent and distinct, each from the other. The reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious over the other group. The search for each of the inventions is not co-extensive particularly with regard to the literature search. Further, the consideration for patentability is different in each case. Thus it would be an undue burden to examine all the above inventions in one application.

4. Because these inventions are distinct for the reasons given above and the search required for each group is not necessarily required by other group, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-VII, restriction for examination purposes as indicated is proper.

6.

Applicant is advised that a reply to this requirement must include an election of species from the elected group for the search purposes.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. This application contains claims directed to the following patentably distinct species of the claimed invention: Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 28, 30 and 32 are generic. If compound of Group I-IV is elected applicants must elect one single compound to be

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examined on merits. If the method of Group V is elected, applicants must elect a particular disease to be examined on the merits.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Eligible for Rejoinder of method claims

In order to be eligible for rejoinder, a claim to a nonelected invention must depend from or otherwise require all the limitations of an allowable claim. A withdrawn claim that does not require all the limitations of an allowable claim will not be rejoined. Furthermore, where restriction was required between a product and a process of making and/or using the product, and the product invention was elected and subsequently found allowable, all claims to a nonelected process invention must depend from or otherwise require all the limitations of an allowable claim for the claims directed to that process invention to be eligible for rejoinder. See MPEP § 821.04(b).

Until elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claim that are not commensurate in scope

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with an allowed product will not be rejoined. See "Guidance on Treatment of Product and process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103 (b)," 1184 O.G. 86 (March 26, 1996).

In order to retain the right to rejoinder, applicant is advised that the claims to the nonelected invention(s) should be amended during prosecution to require the limitations of the elected invention. Failure to do so may result in a loss of the right to rejoinder. Rejoined claims must be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112.

See also MPEP § 804.01.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi, Ph.D. whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Johann Richter, Ph.D. can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D.
PRIMARY EXAMINER